Exhibit 42

2021 FDA Center for Drug Evaluation and Research Director Patrizia Cavazzoni Letter to Dr. Graham Chelius (Dec. 16, 2021)

December 16, 2021

Graham Chelius, M.D.
The Society of Family Planning
The California Academy of Family Physicians

Dear Dr. Chelius:

This letter is to inform you that FDA has completed its review of the Mifepristone Risk Evaluation and Mitigation System (REMS) Program.[1] The agency has determined that the Mifepristone REMS Program continues to be necessary to ensure that the benefits of the drug outweigh the risks. However, we have determined that it must be modified to minimize the burden on the health care delivery system of complying with the REMS and to ensure that the benefits of the drug outweigh the risks. See 21 USC 355-1(g)(4)(B). The modifications to the REMS will consist of: (1) removing the requirement that mifepristone be dispensed only in certain healthcare settings, specifically clinics, medical offices, and hospitals (i.e., the "in-person dispensing requirement"); and (2) adding a requirement that pharmacies that dispense the drug be specially certified.

A REMS Modification Notification letter has been sent to both Applicants subject to the Mifepristone REMS Program. The letter describes the modifications and directs the Applicants to submit prior approval supplements within 120 days. We have also answered a related citizen petition from the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians. That response will be posted in the public docket (Docket No. FDA-2019-P-1534; available at www.regulations.gov).

Sincerely,

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[1] We also note your letter of September 29, 2021 to us on this subject.